K102258

510(k) SUMMARY

JUN 10 2011

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) - Submitter Information	
Name	Integra Burlington MA, Inc.
Address	22 Terry Avenue Burlington, MA 01803
Phone number	781-565-1227
Fax number	781-238-0645
Establishment Registration Number	1222895
Name of contact person	Kevin J. O'Connell
Date prepared	June 8, 2011
807.92(a)(2) - Name of device	
Trade or proprietary name	Integra™ CUSA NXT™ Extended Length Tip
Common or usual name	Ultrasonic Surgical Aspirator
Classification name	Instrument, Ultrasonic Surgical
Classification panel	General and Plastic Surgery
Regulation	unclassified
Product Code(s)	LFL
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	Selector Integra Ultrasonic Surgical Aspirator System, K021989 CUSA EXCEL Ultrasonic Surgical Aspirator System, K981262 CUSA Selector NXT Ultrasonic Tissue Ablation System K081459 Integra Selector Ultrasonic Surgical Aspirator System with Bone Tip K071669
807.92(a)(4) - Device description	
	The Extended Length Tip (ELT) has been designed to be used with the 35kHz Handpiece of the CUSA Selector and CUSA NXT Ultrasonic surgical aspirators. Ultrasonic surgical aspirators facilitate the removal of cellular and other unwanted soft and hard (e.g. bone) tissue. These systems provide selective tissue disintegration with simultaneous irrigation and aspiration. The design of the 35 kHz Fine tip that is currently used with the 35kHz Handpiece has been modified to increase the working length of the device and reduce the bend angle. This will allow the device to be used in procedures where the surgeon requires a longer tip. The ELT consists of a titanium tip, silicone flue and an ultem shroud. The

	distal end of the ELT will have a flat annulus and two pre-aspiration holes The ELT will be supplied sterile and is intended for single use.
807.92(a)(5) Intended use of the device	
Indications for use	The CUSA NXT Extended Length Tip for soft tissue is an accessory to the CUSA NXT and CUSA Selector Ultrasonic Surgical Aspirator Systems that are indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery. The indications for use for the systems is the same as the predicate devices, K071669 and K081459, listed in 807.92(a) (3) above.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

Characteristic	CUSA NXT Extended Length Tip	Selector Integra Ultrasonic Surgical Aspirator System, K021989.	CUSA Selector NXT Ultrasonic Tissue Ablation System K081459.	CUSA EXCEL Ultrasonic Surgical Aspirator System, K981262
System Features				
Oscillation system	Piezoelectric	Piezoelectric	Piezoelectric	Magnetostrictive
Approximate Frequency of Operation	24 kHz & 35 kHz	24 kHz & 35 kHz	24 kHz & 35 kHz	23 kHz & 36 kHz
Tip Amplitude (max)	305 microns (24 kHz) 215 microns (35 kHz)	305 microns (24 kHz) 215 microns (35 kHz)	305 microns (24 kHz) 215 microns (35 kHz)	356 microns (23 kHz) 182 microns (36 kHz)
Irrigation rate	0-50 ml/min	0-50 ml/min	0-50 ml/min	0-30 ml/min.
Suction (Aspiration) system	0-680 mmHg	Up to 600 mmHg	0-680 mmHg	Up to 680 mmHg
vibration of tip	longitudinal	longitudinal	longitudinal	longitudinal
Tips Delivered As	Sterile / Single Use	Sterile / Single Use	Sterile / Single Use	Non Sterile
Tip Specific information	35 kHz Extended Length Tip	35 kHz Neuro Tip	35 kHz Neuro Tip	Curved Extended Micro Tip
Approximate Frequency of Operation	35 kHz	35 kHz	35 kHz	36 kHz
Shroud	Uses a straight shroud, packaged with tip	Uses Shroud with handpiece	Uses Shroud with handpiece	Nosecone
Max Stroke (inches)	0.0069	0.0069	0.0069	0.0076
Vibration of Tip	Longitudinal	Longitudinal	Longitudinal	Longitudinal
Design of distal end	Cylindrical shape with flat annulus	Cylindrical shape with flat annulus	Cylindrical shape with flat annulus	Cylindrical shape with flat annulus
Pre-aspiration holes	Yes	No	No	Yes

Diameter (inches) Inner/outer	0.063/0.077	0.059/0.077	0.059/0.077	0.062/0.076
Length (inches)	9.9	7.2	7.2	4.8
Bend Angle	12°	20°	20°	12°
Material				
Tip	Titanium 6AL4V Grade 5	Titanium 6AL4V Grade 5	Titanium 6AL4V Grade 5	Titanium 6AL4V Grade 5
Flue	Silicone	TPX	TPX	Silicone
Shroud	Ultem	Ultem	Ultem	n/a

807.92(b)(1-2) NONCLINICAL TESTS SUBMITTED

Test	Result
Electromechanical Test – measures frequency, stroke, lateral movement, and power	The test was performed using both the Selector and NXT systems which confirmed that the modified tip has the same stroke, and therefore the same fragmentation power, as the predicate device (35 kHz Fine Tip). This indicates similar heating potential.
IEC 61847 Ultrasonics – Surgical Systems – acoustic power transfer	The modified tip has less acoustic power transfer in liquid as the predicate device (35 kHz Fine Tip, K021989). This indicates reduced heating potential.
Measurement of tissue removal rate and power used during tissue removal rate	The modified tip and predicate device (35 kHz Fine Tip, K021989) remove tissue at an equivalent rate, using equivalent power.
Measurement of Thermal Rise During Ultrasonic Aspiration of Representative Tissue	Thermal rise in tissue field during tissue removal was found to be less for the new tip than the predicate device (35 kHz Fine Tip, K021989).
Biocompatibility	Since the modified device uses materials that have the same chemical formulations, same manufacturing and same sterilization processes as in the predicate device, additional testing was not performed. However, tests results on the predicate device material was included in the submission

807.92(b)(3) CONCLUSIONS DRAWN FROM NON-CLINICAL DATA

Testing using the Selector and NXT systems confirmed that the performance of the modified tip was the same as existing tips for frequency, stroke, lateral movement and quiescent power. Based on the analysis of the design and the performance testing, the heating potential of the new tip is the same or less than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Integra
c/o Kevin J. O'Connell
Director, Regulatory Affairs
22 Terry Avenue
Burlington, MA 01803

JUN 10 2011

Re: K102258
Trade/Device Name: CUSA NXT Extended Length Tip, an accessory of the CUSA NXT and CUSA Selector Ultrasonic Surgical Aspirator Systems
Regulation Number: Unclassified
Regulation Name: Ultrasonic Surgical Instrument
Regulatory Class: Unclassified
Product Code: LFL
Dated: March 24, 2011
Received: March 25, 2011

Dear Mr. O'Connell

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): K102258

Device Name: Integra CUSA NXT Extended Length Tip

Indications For Use:

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PRESCRIPTION USE X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

CGH

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102258